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Being similar to indications for use and technological construction to other Biopsy Devices, the Cook® Sidearm Core Tissue Biopsy Device meets requirements for substantial equivalency according to section 510(k) guidelines, justifying for commercial sale.

I. 510(k) SUMMARY

Submitted By:

Cindy Rumple
Cook Urological, Incorporated
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
December 5, 2003

Device

Trade Name:	Cook® Sidearm Core Tissue Biopsy Device/Set
Proposed Classification Name:	Instrument, Biopsy Class II 78 KNW

Predicate Devices:

The Cook® Sidearm Core Tissue Biopsy Device is comparable to existing predicate devices in distribution including the Magnum Biopsy System (K871390) manufactured by C.R. Bard, Incorporated, the EMS Biopsy Instrument (K930083) manufactured by Engineered Medical Systems, the High Speed Core Cut Biopsy Device (K905556) manufactured by BIP USA, Incorporated, the Manan Pro-Mag Automatic Biopsy Device (K914874) manufactured by Manan Medical Products, Incorporated, and the (Roth) Spiral Rotating Prostatic Biopsy Needle (K863385), manufactured by Cook Urological, Incorporated.

Device Description:

The Cook® Sidearm Core Tissue Biopsy Device/Set is used as an automated biopsy instrument to obtain multiple core tissue sampling from sites including, but not limited to, the prostate, kidney, liver, lung, breast, lymph nodes and different tumors for histological evaluation. The Cook® Sidearm Core Tissue Biopsy Device/Set allows adjustment for an 18mm or 23mm sample, allows the sample to be easily exposed, is a one-handed operation, and will not fire when the sample size is in the incorrect position. The construction of the Cook® Sidearm Core Tissue Biopsy Device is Ryton, Anodized aluminum, Silicone, Delrin, and Stainless Steel. The construction of the Cook® Sidearm Needles are stainless steel and polycarbonate.

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Biocompatibility

The needles are constructed of stainless steel which is a well known material in the medical community and polycarbonate, which does not come into contact with the patient. The biopsy device does come into contact with the patient; therefore, biocompatibility is not warranted.

Substantial Equivalence:

The device and needles will be manufactured according to specified controls and a Quality Assurance Program. The Cook® Sidearm Core Tissue Biopsy Device/Set will undergo packaging similar to devices currently marketed and distributed by Cook Urological, Incorporated. Being similar with respect to indications for use, materials, and physical construction to predicate devices, this device set meets the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2004

Ms. Cindy Rumple
Regulatory Affairs Technical Writer
Cook Urological, Incorporated
1100 W. Morgan Street
SPENCER IN 47460

Re: K041544
Trade/Device Name: Cook® Sidearm Core Tissue Biopsy Device/Set
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Codes: 78 KNW and FCG
Dated: June 4, 2004
Received: June 9, 2004

Dear Ms. Rumple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K041544

Device Name: Cook® Sidearm Core Tissue Biopsy Device/Set (Not Yet Assigned)

Indications for Use: The Cook® Sidearm Core Tissue Biopsy Device/Set is used as an automated biopsy instrument to obtain multiple cores of tissue sampling from sites including, but not limited to the prostate, kidney, liver, lung, breast, lymph nodes, and different tumors for histological evaluation.

Prescription Use___X___ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041544